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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Irina Nazarenko

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EXAMINER

STAPLES, MARK

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/599,594	<b>Applicant(s)</b> NAZARENKO ET AL.	
	<b>Examiner</b> Mark Staples	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11,12,14,15,17-19,59,63-67,78 and 79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11,12,14,15,17-19,59 and 63-67 is/are rejected.
- 7) ☒ Claim(s) 78 and 79 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Change of Examiner***

1. The Examiner of record has changed. Please address future correspondence to Examiner Staples whose telephone number is (571) 272 9053).

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/29/2008 has been entered.

3. Claims 11, 12, 14, 15, 17-19, 59, 63-67, 78, and 79 are pending and at issue.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Rejections are Maintained**

***Claim Rejections Maintained - 35 USC § 103***

4. The rejection of claims 11, 12, 14, 15, 17-19, 59 and 63-67 under 35 U.S.C. 103(a) as being unpatentable over Horn et al (U.S. Patent 6,465,175) in view of Tyagi et al (U.S. Patent 6,037,130) is maintained.

Applicant's arguments filed 07/06/2007 have been fully considered but they are not persuasive. Applicant argues that the modifying the methods of Horn et al. to incorporate the single fluorescent labeled probe of Horn et al. into amplification product would require a substantial modification of those probes taught by Tyagi et al., which include both a fluorescent label and a quencher dye. However, deleting the quencher dye of Tyagi et al. is not a substantial modification.

But regardless and more importantly, Tyagi et al. are relied upon for the teaching that primers and probes, including hairpin probes, can be incorporated into PCR product (a type of amplification product, see column 18, example 5). It is Horn et al. who are relied upon for the teaching that fluorescence and quenching can be accomplished with a single fluorescent label (see column 17 and 18, example 6). Thus as both Tyagi et al. and Horn et al. teach detection with fluorescent and quenched probes, and Tygai et al. teach that probes with a fluorescent label and quencher dye can be incorporated into PCR product; it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to modify the methods of Horn et al. by incorporating the probes of Horn et al. with a single fluorescent label into PCR product.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Tyagi et al. and Horn et al. teach fluorescence detection by altering the fluorescence signal of a fluorescent label. Tyagi et al. and Horn et al. both teach fluorescence and quenching fluorescence. Tyagi et al. specifically (but not solely) teach that fluorescence of single stranded probes can be quenched with a quencher dye, whereas Horn et al. specifically (but not solely) teach that fluorescence of single stranded probes can be quenched through hybridizing to a nucleic acid to form a double stranded complex.

Contrary to Applicant's argument, the principle of the methods of Horn et al. and Tyagi et al. is the same and that principle is the quenching of fluorescence. Horn et al. employ this principle with a single fluorescent label on a single stranded probe which is quenched in proximity to another strand (through hybridization and formation of the double strand). Tyagi et al. employ this principle with a fluorescent label and a quencher label, where the fluorescent label is quenched in proximity to the quencher label. As one of ordinary skill in the art would have understood this principle, one would have been motivated to use the probe of Horn et al. with a single fluorescent label, as a

separate quenching dye would not have been necessary (see pages 6 and 7 of Office action mailed on 08/27/2007)

Thus the claimed invention was obvious over the teaching of Horn et al. in view of Tyagi et al. and the rejection is maintained.

**Claim Objections Maintained**

**Allowable Subject Matter**

5. The objections to claims 78-79 are maintained as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims (see sections 7 and 8 of the Office Action mailed on 08/29/2007).

**Conclusion**

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples

/M. S./

Examiner, Art Unit 1637

May 22, 2008

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637